UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/433,646	05/04/95	FAHIM	R MIS/MS-1038

EXAMINER: FREED, R

ART UNIT: 1802 | PAPER NUMBER: 4

18M1/0703

SIM & MCBURNEY
330 UNIVERSITY AVENUE
SUITE 701
TORONTO CANADA
M5G 1R7

DATE MAILED: 07/03/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-37 are pending in the application.
   Of the above, claims 18-37 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-17 are rejected.
5. ☐ Claims _____ are objected to.
6. ☒ Claims 1-37 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☒ The ~~corrected or substitute~~ drawings have been received on 5/14/95. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☒ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

Election/Restriction

15. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-17, drawn to a process for preparing an agglutinogen preparation from Bordetella, classified in Class 436, subclass 543.

Group II. Claims 18-35, drawn to a composition of agglutinogen 2 and 3 from Bordetella, classified in Class 424, subclass 240.1.

Group III. Claims 36-37, drawn to a method of immunizing a host with an agglutinogen composition from Bordetella, classified in Class 424, subclass 253.1.

16. The inventions are distinct, each from the other because of the following reasons:

a. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the product as claimed can be made by a materially different process which includes shearing the cells to release the

agglutinogens and subsequent purification by precipitation with ammonium sulphate. Additionally the process as claimed can be used to make another materially different product such as a composition that includes agglutinogen 1.

b. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as for purification of antibodies to Bordetella agglutinogens from a sample.

17. Because these inventions are distinct for the reasons given above and the search strategy required for Group I is not required for Groups II and III, and because Groups I and II have acquired a separate status in the art from Group III as shown by their different classification restriction for examination purposes as indicated is proper.

18. During a telephone conversation with Michael Stewart on June 12, 1996 a provisional election was made with traverse to

prosecute the invention of group I, claims 1-17. Affirmation of this election must be made by applicant in responding to this Office action. Claims 18-37 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

19. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

20. Claim 13 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 13, the use of the trademark Sephadex 6B (which appears to misspelled as Septhadex) renders the claim indefinite in that the material encompassed by the trademark is not fixed over time. Substitution of the generic description would obviate this rejection.

21. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 86 S.Ct. 684, 15 L.Ed. 2nd 545 (1966), 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103 are summarized as follows:

1. Determining the scope and contents of the prior art;
2. Ascertaining the differences between the prior art and the claims at issue; and
3. Resolving the level of ordinary skill in the pertinent art.

Claims 1-8, 12-14 and 17 are rejected under 35 U.S.C. § 103 as being unpatentable over Fredriksen et al. in view of Jackson et al.

Fredriksen et al. teaches purification of agglutinogen 3 from B.pertussis. The cell surface antigens were extracted by

shearing the cells, separating the precipitate from the supernatant by centrifugation and subjecting the crude extract to incubation at 80 °C for 5 min. The aggregated material was removed by centrifugation and the supernatant was then subjected to precipitation with ammonium sulphate. The precipitate was collected and solubilized. The solubilized sample was again subjected to centrifugation to remove insolubles and the supernatant was purified by gel filtration chromatography. See page 189. Fredriksen et al. teaches on page 190 that no loss of agglutinogen activity occurs if the crude extract were incubated for 30 minutes. At page 194, Fredriksen et al. teaches that heat treatment is advantageous because 30% of protein that is not of interest is removed.

Jackson et al. teaches purification of pertactin from B.pertussis by placing the cells in a 4M solution of urea, then separating the precipitate from the supernatant by centrifugation. In order to obtain pertactin from the supernatant it is subjected to ultrafiltration. Most importantly, Jackson et al. teaches that the supernatant contains agglutinogens which are separated from the pertactin by the ultrafiltration. See column 4, lines 12-20.

It would have been obvious to the ordinarily skilled artisan at the time the invention was made to have suspended the cell paste of Fredriksen et al. in urea in order to remove the

agglutinogens from the surface of B.pertussis as taught by Jackson et al. instead of using the mechanical shearing process taught by Fredriksen et al. since the examiner takes Official Notice of the equivalent function of these two method of separating cell surface proteins and the selection of any of these known equivalents would be within the level of ordinary skill in the art depending on the availability of a homogenizer or that of urea.

Neither Fredriksen et al. not Jackson et al. teaches concentrating the crude extract before further processing to purify the agglutinogens therefrom. However, it is the position of the examiner that such a step would have been an obvious matter of design choice to the skilled technician as such a step was extremely well known in protein purification schemes (see Jackson et al. which teaches membrane filtration to concentrate the pertactin).

As regards the material of the column, it is the position of the examiner that it would have been obvious to the ordinarily skilled artisan at the time the invention was made used any of the well known chromatographic materials as a matter of design choice since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use. *In re Leshin*, 125 USPQ 416.

Neither Fredriksen et al. not Jackson et al. teaches sterile

filtering the purified agglutinogen composition. However it would have been obvious to the ordinarily skilled artisan at the time the invention was made to have sterile filtered the composition since it was notoriously well known in the art sterile filtering purified proteins from a sample maintains longer storage life thereof.

22. Claims 9-11 are rejected under 35 U.S.C. § 103 as being unpatentable over Fredriksen et al. in view of Jackson et al. as applied to claims 1-8, 12-14 and 17 above and further in view of Gotto.

Fredriksen et al. as modified by Jackson et al. teaches ammonium sulphate precipitation rather than using polyethylene glycol. Gotto shows that PEG and ammonium sulphate are equivalent reagents for protein precipitation and may be used in protein purification schemes for B.pertussis. Therefore, because these two protein precipitation reagents were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute PEG for ammonium sulphate.

As to the claimed concentration of PEG to effect the precipitation, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have determined the amount of precipitating reagent necessary, since

it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

23. Claims 15-16 are rejected under 35 U.S.C. § 103 as being unpatentable over Fredriksen et al. as modified by Jackson et al. as applied to claims 1-8, 12-14 and 17 above, and further in view of Kieff et al.

Fredriksen et al. as modified by Jackson et al. does not teach absorbing the purified protein onto a mineral salt such as alum.

Keiff et al. teaches a vaccine composition of a protein absorbed onto alum. See column 9, lines 56-58.

It would have been obvious to the ordinarily skilled artisan at the time invention was made to have absorbed the purified agglutinogen composition of Fredriksen et al. as modified by Jackson et al. in order to use the composition in a vaccine composition.

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Dorssers et al. teaches sterile filtering a purified protein.

Malley teaches a vaccination composition of an antibody absorbed to alum.

Cowell et al. teaches purification of agglutinogens by shearing the protein from the cell surface and subsequently precipitating the agglutinogens therefrom by ammonium sulfate precipitation.

Rutter et al. teaches a vaccine composition which includes fimbriae bearing agglutinogen 2 and 3.

Nakase et al. teaches purification of K-agglutinogen from B.pertussis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel Freed whose telephone number is (703) 308-3896.

Any facsimile transmission should be directed to (703) 308-4242 which is the facsimile number designated for all draft and official communications for Art Unit 1802.

Rachel Freed
June 21, 1996

JAMES C. HOUSEL 6/24/96
SUPERVISORY PATENT EXAMINER
GROUP 180